NOTE: Exhibits E and G are the same due to a lettering error.

SELECTED STATE STATUTES

EXHIBIT E.

Five statutory schemes for Prescription Drug Monitoring Programs are set forth in this Exhibit. Kentucky is one of the oldest and most successful programs in the United States. Florida, Oklahoma and Vermont are newcomers to the number of states which have programs and have profited from the experience and mistakes of other states in enacting their legislation. Virginia, our sister state to the South, has a very workable and successful program.

[1] The Florida Statute of all provisions relating to the Prescription Drug Monitoring Program is contained in one statute. Without titles to the various sections, we have given a descriptive title to the content of that section.

NOTE: Exhibits E and G are the same due to a lettering error.

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TITLE 63. PUBLIC HEALTH AND SAFETY
CHAPTER 2. UNIFORM CONTROLLED DANGEROUS SUBSTANCES ACT
ARTICLE III. REGULATION OF MANUFACTURE, DISTRIBUTION, DISPENSING, PRESCRIBING, ADMINISTERING AND USING FOR SCIENTIFIC PURPOSES OF CONTROLLED DANGEROUS SUBSTANCES
ANTI-DRUG DIVERSION ACT

63 Okl. St. § 2-309A (2009)

§ 2-309A. Short title

Section 2-309A et seq. of this title shall be known and may be cited as the "Anti-Drug Diversion Act".

§ 2-309B. Definitions

For the purposes of the Anti-Drug Diversion Act:

1. "Bureau" means the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

2. "Dispenser" means a person who distributes a Schedule II controlled dangerous substance, but does not include a licensed hospital pharmacy or a licensed nurse or medication aide who administers such a substance at the direction of a licensed physician;

3. "Dispenser's registration number" means the dispenser's Oklahoma Bureau of Narcotics and Dangerous Drugs Control registration number or, in the case of a pharmacist, the National Association of Boards of Pharmacy number for the pharmacy where the dispensation is made;

4. "Exception report" means an output of data indicating Schedule II controlled dangerous substance dispensation which is outside expected norms for a prescriber practicing a particular specialty or field of health care, for a dispenser doing business in a particular location, or for a recipient;

5. "Recipient's identification number" means the unique number contained on a recipient's valid passport, military identification card, driver license, or valid identification card issued pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the recipient is not a resident of the State of Oklahoma, or, if the recipient is less than eighteen (18) years old and has no such identification, the unique number contained on the recipient's parent's or guardian's valid passport, military identification card, driver license, or valid identification card issued pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the parent or guardian is not a resident of the State of Oklahoma, or, if the controlled dangerous substance is obtained for an animal, the unique number contained on the animal owner's valid driver license, or valid identification card issued pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the owner is not a resident of the State of Oklahoma;

6. "Registrant" means a person, persons, corporation or other entity who has been issued by the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control a registration pursuant to Section 2-302 of this title; and

7. "State" means any state, territory, or possession of the United States, the District of Columbia, or foreign nation.

§ 2-309C. Dispensers of Schedule II, III, IV or V controlled dangerous substances--Transmittal of certain information to central repository--Willful failure to transmit--Monitoring of pseudoephedrine product sales

A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance, except Schedule V substances that contain any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers shall transmit to a central repository designated by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control using the American Society for Automation in Pharmacy's (ASAP) Telecommunications

NOTE: Exhibits E and G are the same due to a lettering error.

Format for Controlled Substances version designated in rules by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, the following information for each dispensation:

1. Recipient's name, when feasible to submit;
2. Recipient's identification number;
3. National Drug Code number of the substance dispensed;
4. Date of the dispensation;
5. Quantity of the substance dispensed;
6. Prescriber's United States Drug Enforcement Agency registration number; and
7. Dispenser's registration number.

B. The information required by this section shall be transmitted:

1. On an electronic device which is compatible with the receiving device of the central repository or by computer diskette, magnetic tape, CD-ROM or in a format or other media designated acceptable by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control; and
2. Within thirty (30) days of the time that the substance is dispensed.

C. Willful failure to transmit information as required by this section shall be a misdemeanor punishable, upon conviction, by not more than one (1) year in the county jail, or by a fine of not more than One Thousand Dollars ($ 1,000.00), or by both such imprisonment and fine, or administrative action may be taken pursuant to Section 2-304 of this title.

D. The Director of the Bureau shall have the authority to allow paper submissions on the universal claim form, if the dispenser has an appropriate hardship.

E. The Oklahoma Bureau of Narcotics and Dangerous Drugs Control is authorized, by any funds available to it, to implement a real-time electronic logbook to monitor the sale of Schedule V products containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers. Dispensers of such pseudoephedrine products shall report all such sales electronically pursuant to rules promulgated by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. The reporting requirements of this title do not apply to any lawful sale of a Schedule V product containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers, until such time that:

1. The Oklahoma Bureau of Narcotics and Dangerous Drugs Control implements a statewide real-time logbook that authorizes purchases and records purchaser information statewide; and
2. The Oklahoma Bureau of Narcotics and Dangerous Drugs Control adopts rules for the reporting of sales of Schedule V product containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers.

§ 2-309D. Central repository information--Confidentiality--Access--Disclosure--Penalties--Liability

A. The information collected at the central repository pursuant to the Anti-Drug Diversion Act shall be confidential and shall not be open to the public. Access to the information shall be limited to:

1. Peace officers certified pursuant to Section 3311 of Title 70 of the Oklahoma Statutes who are employed as investigative agents of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
2. The United States Drug Enforcement Administration Diversion Group Supervisor;
3. The executive director or chief investigator, as designated by each board, of the following state boards:
   a. Board of Podiatric Medical Examiners,
   b. Board of Dentistry,
   c. Board of Pharmacy,
   d. State Board of Medical Licensure and Supervision,
   e. State Board of Osteopathic Examiners, and
   f. State Board of Veterinary Medical Examiners;

provided, however, that the executive director or chief investigator of each of these boards shall be limited to access to information relevant to licensees of the employing board of such executive director or chief investigator; and

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4. A multicounty grand jury properly convened pursuant to the Multicounty Grand Jury Act, Sections 350 through 363 of Title 22 of the Oklahoma Statutes.

B. This section shall not prevent the disclosure, at the discretion of the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, of investigative information to peace officers and investigative agents of federal, state, county or municipal law enforcement agencies, district attorneys and the Attorney General in furtherance of criminal investigations or prosecutions within their respective jurisdictions, and to registrants in furtherance of efforts to guard against the diversion of controlled dangerous substances.

C. Any unauthorized disclosure of any information collected at the central repository provided by the Anti-Drug Diversion Act shall be a misdemeanor. Violation of the provisions of this section shall be deemed willful neglect of duty and shall be grounds for removal from office.

D. Notwithstanding the provisions of subsection B, registrants shall have no requirement or obligation to access or check the information in the central repository prior to dispensing or administering medications or as part of their professional practices. Registrants shall not be liable to any person for any claim of damages as a result of accessing or failing to access the information in the central repository and no lawsuit may be predicated thereon. Nothing herein shall be construed to relieve a registrant from any duty to monitor and report the sales of certain products pursuant to subsection E of Section 2-309C of this title.

§ 2-309E. Central repository information--Control of access

All access to information in the central repository shall be controlled by and made through the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.

§ 2-309F. Central repository--Powers, duties and responsibilities--Contract with vendor to serve as

A. The central repository provided by the Anti-Drug Diversion Act shall:

1. Be capable of providing the collected information in forms required by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, including but not limited to, dispensations by prescriber name or registration number, dispenser name or registration number, recipient name or identification number, type of substance, frequency, quantity, and location of dispensation;
2. Provide the Bureau with continual, twenty-four-hour per day, on-line access to the collected information;
3. Secure the collected information against access by unauthorized persons;
4. Provide the Bureau, in a reasonable time, with all collected information in a format readily usable by the Bureau, in the event the relationship between the state and central repository is terminated; and
5. Not withhold access to the collected information for any reason other than failure of the Bureau to timely pay agreed fees and charges for use of the central repository.

B. The Bureau is authorized to enter into a contract with a vendor to serve as the central repository provided for in the Anti-Drug Diversion Act or to purchase the necessary equipment to create the central repository within the Bureau.

§ 2-309G. Development of criteria for production of exception reports out of information collected

The Oklahoma Bureau of Narcotics and Dangerous Drugs Control shall develop criteria for the production of exception reports out of the information collected at the central repository. In developing these criteria, the Bureau shall seek the counsel of the following entities:

1. Board of Podiatric Medical Examiners;
2. Board of Dentistry;
3. Board of Pharmacy;
4. State Board of Medical Licensure and Supervision;
5. State Board of Osteopathic Examiners;
6. State Board of Veterinary Medical Examiners;

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7. Oklahoma Podiatric Medical Association;
8. Oklahoma Dental Association;
9. Oklahoma Pharmaceutical Association;
10. Oklahoma State Medical Association;
11. Oklahoma Osteopathic Association; and
12. Oklahoma Veterinary Medical Association.

§ 2-309H. Implementation and enforcement of act--Rules and regulations

The Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control shall promulgate and adopt rules to implement and enforce the Anti-Drug Diversion Act.

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TITLE 46. CRIMES (Chs. 775-896)
CHAPTER 893. DRUG ABUSE PREVENTION AND CONTROL

GO TO FLORIDA STATUTES ARCHIVE DIRECTORY

Fla. Stat. § 893.055 (2009)

§ 893.055. Prescription drug monitoring program

(1) As used in this section, the term:

(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

(b) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c) "Dispenser" means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(d) "Health care practitioner" or "practitioner" means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.

(e) "Health care regulatory board" means any board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g) "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

(i) "Law enforcement agency" means the Department of Law Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(2) (a) By December 1, 2010, the department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information

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(EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b) The department, when the direct support organization receives at least $ 20,000 in nonstate moneys or the state receives at least $ 20,000 in federal grants for the prescription drug monitoring program, and in consultation with the Office of Drug Control, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

(c) All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.

(3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:

(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c) The full name, address, and date of birth of the person for whom the prescription was written.

(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g) Other appropriate identifying information as determined by department rule.

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

NOTE: Exhibits E and G are the same due to a lettering error.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.

(d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

(e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.

(f) A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

(6) The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

(7) (a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b) A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551.

(c) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.

2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be

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validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database. Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1. Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(8) To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c) Increased coordination among partners participating in the prescription drug monitoring program.

(d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(5)(f), the department shall comply with the competitive-solicitation requirements under s. 287.057 for the procurement of any goods or services required by this section.

(11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

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(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support organization. The director may designate employees of the Office of Drug Control, state employees other than state employees from the department, and any other nonstate employees as appropriate, to serve on the board. Members of the board shall serve at the pleasure of the director of the Office of Drug Control. The director shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

(d) The direct-support organization shall operate under written contract with the Office of Drug Control. The contract must, at a minimum, provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.

2. Submission of an annual budget for the approval of the Office of Drug Control.

3. Certification by the Office of Drug Control in consultation with the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

4. The reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to exist, of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.

5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the Office of Drug Control and the direct-support organization.

7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.

b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).

c. Providing funds for future enhancements of the program within the intent of this section.

d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

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e. Providing funds for travel expenses.

f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.

g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

(e) The activities of the direct-support organization must be consistent with the goals and mission of the Office of Drug Control, as determined by the office in consultation with the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the director of the Office of Drug Control for any activities in support of the prescription drug monitoring program before undertaking those activities.

(f) The Office of Drug Control, in consultation with the department, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the Office of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the Office of Drug Control if the direct-support organization is no longer approved by the Office of Drug Control to operate in the best interests of the state.

(g) The Office of Drug Control, in consultation with the department, may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h) The Office of Drug Control may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.

(j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the monitoring program to support the program enhancements.

NOTE: Exhibits E and G are the same due to a lettering error.

(14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

(15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.

(16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.

Rulemaking authority is referenced to the following statutes:

1. Fla. Stat. §458.309 (2009). Rulemaking Authority (Medical Practice)
2. Fla. Stat. §459.005 (2009). Rulemaking Authority (Osteopathic Medicine)

NOTE: Exhibits E and G are the same due to a lettering error.

CODE OF VIRGINIA
TITLE 54.1. PROFESSIONS AND OCCUPATIONS
SUBTITLE III. PROFESSIONS AND OCCUPATIONS REGULATED BY BOARDS WITHIN THE DEPARTMENT OF HEALTH PROFESSIONS
CHAPTER 25.2. PRESCRIPTION MONITORING PROGRAM
Va. Code Ann. § 54.1-2519 (2009)

§ 54.1-2519. Definitions

As used in this article, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means all controlled substances included in Schedules II, III, and IV that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2520. Program establishment; Director's regulatory authority

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, III, and IV controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.).

B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

NOTE: Exhibits E and G are the same due to a lettering error.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Prescription Monitoring Program.

§ 54.1-2521. Reporting requirements

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number.
7. The dispenser's identifier number.
8. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.
9. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2522. Reporting exemptions

The dispensing of covered substances under the following circumstances shall be exempt from the reporting requirements set forth in § 54.1-2521:

1. Dispensing of manufacturers' samples of such covered substances or of covered substances dispensed pursuant to an indigent patient program offered by a pharmaceutical manufacturer.
2. Dispensing of covered substances by a practitioner of the healing arts to his patient in a bona fide medical emergency or when pharmaceutical services are not available.
3. Administering of covered substances.
4. Dispensing of covered substances within an appropriately licensed narcotic maintenance treatment program.
5. Dispensing of covered substances to inpatients in hospitals or nursing facilities licensed by the Board of Health or facilities that are otherwise authorized by law to operate as hospitals or nursing homes in the Commonwealth.
6. Dispensing of covered substances to inpatients in hospices licensed by the Board of Health.
7. Dispensing of covered substances by veterinarians to animals within the usual course of their professional practice.
8. Dispensing of covered substances as otherwise provided in the Department's regulations.

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription

NOTE: Exhibits E and G are the same due to a lettering error.

Monitoring program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent designated by the superintendent of the Department of State Police to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of this title.

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific dispenser or specific prescriber to an agent of the United States Drug Enforcement Administration with authority to conduct drug diversion investigations.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or the prescriber is initiating treatment of such recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.

4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.

6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.

NOTE: Exhibits E and G are the same due to a lettering error.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall use the information only for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

§ 54.1-2523.1. Criteria for indicators of misuse; Director's authority to disclose information; intervention

The Director shall develop, in consultation with an advisory panel, criteria for indicators of misuse and a method for analysis of data collected by the Prescription Monitoring Program using the criteria for indicators of misuse. Upon the development of such criteria and data analysis, the Director may, in addition to the discretionary disclosure of information pursuant to § 54.1-2523, disclose information using the criteria that indicates potential misuse by recipients of covered substances to their specific prescribers for the purpose of intervention to prevent such misuse.

§ 54.1-2523.2. Authority to access database

Any prescriber authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to up to two health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions, and (ii) employed at the same facility and under the direct supervision of the prescriber.

§ 54.1-2524. Immunity from liability

A. The Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the accuracy or inaccuracy of any information reported to and compiled and maintained by the Department pursuant to this chapter.

Further, the Director and the employees of the Department of Health Professions shall not be liable for any civil damages resulting from the disclosure of or failure to disclose any information in compliance with subsections B and C of § 54.1-2523 and the Department's regulations.

B. In the absence of gross negligence or willful misconduct, prescribers or dispensers complying in good faith with the reporting requirements of this chapter shall not be liable for any civil damages for any act or omission resulting from the submission of such required reports.

§ 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties

A. It shall be unlawful for any person having access to the confidential information in the possession of the Program or any data or reports produced by the program to disclose such confidential information except as provided in this chapter. Any person having access to the confidential information in the possession of the program or any data or reports produced by the program who discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

NOTE: Exhibits E and G are the same due to a lettering error.

B. It shall be unlawful for any person who lawfully receives confidential information from the Prescription Monitoring Program to redisclose or use such confidential information in any way other than the authorized purpose for which the request was made. Any person who lawfully receives information from the Prescription Monitoring Program and discloses such confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.

C. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

§ 54.1-2526. Exemption of information systems from provisions related to the Virginia Information Technologies Agency

The provisions of Chapter 20.1 (§ 2.2-2005 et seq.) of Title 2.2 shall not apply to the Prescription Monitoring Program pursuant to this chapter operated by the Department of Health Professions until July 1, 2012, unless an alternate date is mutually agreed upon.

NOTE: Exhibits E and G are the same due to a lettering error.

The Vermont Statutes

Title 18: Health

Chapter 84A: VERMONT PRESCRIPTION MONITORING SYSTEM

§ 4281. Legislative intent

The general assembly recognizes the important public health benefits of the legal medical use of controlled substances and also the significant risk to public health that can arise due to the abuse of those substances. It is the intent of this chapter to create the Vermont prescription monitoring system, which will provide an electronic database and reporting system for electronic monitoring of prescriptions for Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4282. Definitions

As used in this chapter:

(1) "Dispenser" shall mean any person who "dispenses" or engages in "dispensing" as those terms are defined in subdivision 2022(5) of Title 26.

(2) "Health care provider" shall mean an individual licensed, certified, or authorized by law to provide professional health care service in this state to an individual during that individual's medical or dental care, treatment, or confinement.

(3) "Trained law enforcement officer" shall include any officer designated by the department of public safety who has completed a training program established by rule by the department of health, which is designed to ensure that officers have the training necessary to use responsibly and properly any information that they receive from VPMS.

(4) "VPMS" shall mean the Vermont prescription monitoring system established under this chapter. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4283. Creation; implementation

(a) Contingent upon the receipt of funding, the department may establish an electronic database and reporting system for monitoring Schedules II, III, and IV controlled substances, as defined in 21 C.F.R. Part 1308, as amended and as may be amended, that are dispensed within the state of Vermont by a health care provider or dispenser or dispensed to an address within the state by a pharmacy licensed by the Vermont board of pharmacy.

(b) As required by the department, every dispenser who is licensed by the Vermont board of pharmacy shall report to the department in a timely manner data for each controlled substance in Schedules II, III, and IV, as amended and as may be amended, dispensed to a patient within Vermont. Reporting shall not be required for:

(1) a drug administered directly to a patient; or

(2) a drug dispensed by a health care provider at a facility licensed by the department, provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of 48 hours.

(c) Data for each controlled substance that is dispensed shall include the following:

(1) patient identifier, which may include the patient's name and date of birth;

(2) drug dispensed;

(3) date of dispensing;

NOTE: Exhibits E and G are the same due to a lettering error.

(4) quantity and dosage dispensed;
(5) the number of days' supply;
(6) health care provider; and
(7) dispenser.

(d) The data shall be provided in the electronic format defined by the department. To the extent possible, the format shall not require data entry in excess of that required in the regular course of business. Electronic transmission is not required if a waiver has been granted by the department to an individual dispenser. The department shall strive to create VPMS in a manner that will enable real-time transmittal to VPMS and real-time retrieval of information stored in VPMS.

(e) It is not the intention of the department that a health care provider or a dispenser shall have to pay a fee or tax or purchase hardware or proprietary software required by the department specifically for the establishment, maintenance, or transmission of the data. The department shall seek grant funds and take any other action within its financial capability to minimize any cost impact to health care providers and dispensers.

(f) The department shall purge from VPMS all data that is more than six years old.

(g) The commissioner shall develop and provide advisory notices, which shall make clear that all prescriptions for controlled drugs in Schedules II, III, and IV are entered into a statewide database in order to protect the public. The notices shall be distributed at no cost to dispensers and health care providers who are subject to this chapter.

(h) A dispenser shall be subject to discipline by the board of pharmacy or by the applicable licensing entity if the dispenser intentionally fails to comply with the requirements of subsection (b), (c), or (d) of this section. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4284. Protection and disclosure of information

(a) The data collected pursuant to this chapter shall be confidential, except as provided in this chapter, and shall not be subject to public records law. The department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in this section.

(b) The department shall be authorized to provide data to only the following persons:

(1) A patient or that person's health care provider, or both, when VPMS reveals that a patient may be receiving more than a therapeutic amount of one or more regulated substances.

(2) A health care provider or dispenser who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient.

(3) A designated representative of a board responsible for the licensure, regulation, or discipline of health care providers or dispensers pursuant to a bona fide specific investigation.

(4) A patient for whom a prescription is written, insofar as the information relates to that patient.

(5) The relevant occupational licensing or certification authority if the commissioner reasonably suspects fraudulent or illegal activity by a health care provider. The licensing or certification authority may report the data that are the evidence for the suspected fraudulent or illegal activity to a trained law enforcement officer.

(6) The commissioner of public safety, personally, if the commissioner of health personally makes the disclosure, has consulted with at least one of the patient's health care providers, and believes that the disclosure is necessary to avert a serious and imminent threat to a person or the public.

(7) Personnel or contractors, as necessary for establishing and maintaining the VPMS.

(c) A person who receives data or a report from VPMS or from the department shall not share that data or report with any other person or entity not eligible to receive that data pursuant to subsection (b) of this section. Nothing shall restrict the right of a patient to share his or her own data.

(d) The commissioner shall offer health care providers and dispensers training in the proper use of information they may receive from VPMS. Training may be provided in collaboration with professional associations representing health care providers and dispensers.

NOTE: Exhibits E and G are the same due to a lettering error.

(e) A trained law enforcement officer who may receive information pursuant to this section shall not have access to VPMS except for information provided to the officer by the licensing or certification authority.

(f) The department is authorized to use information from VPMS for research and public health promotion purposes provided that data are aggregated or otherwise de-identified.

(g) Knowing disclosure of transmitted data to a person not authorized by subsection (b) of this section, or obtaining information under this section not relating to a bona fide specific investigation, shall be punishable by imprisonment for not more than one year or a fine of not more than $1,000.00, or both, in addition to any penalties under federal law. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4285. Immunity

A dispenser or health care provider shall be immune from civil, criminal, or administrative liability as a result of any action made in good faith pursuant to and in accordance with this chapter, but nothing in this section shall be construed to establish immunity for the failure to follow standards of professional conduct or the failure to exercise due care in the provision of services. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4286. Advisory committee

(a)(1) The commissioner shall establish an advisory committee to assist in the implementation and periodic evaluation of VPMS.

(2) The department shall consult with the committee concerning any potential operational or economic impacts on dispensers and health care providers related to transmission system equipment and software requirements.

(3) The committee shall develop guidelines for use of VPMS by dispensers and health care providers and shall make recommendations concerning under what circumstances, if any, the department shall or may give VPMS data, including data thresholds for such disclosures, to law enforcement personnel. The committee shall also review and approve advisory notices prior to publication.

(b) The advisory committee shall be chaired by the commissioner or his or her designee and shall include the following members:

(1) the deputy commissioner for alcohol and drug abuse programs;
(2) a representative from the Vermont medical society;
(3) a representative from the American college of emergency physicians-Vermont chapter;
(4) a representative from the Vermont state nurses association;
(5) a representative from the Vermont board of medical practice;
(6) a representative from the Vermont board of pharmacy;
(7) a pharmacist from the Vermont pharmacists association;
(8) a representative of the Vermont state dental society;
(9) the commissioner of public safety;
(10) a representative of the Vermont attorney general;
(11) a representative of the Vermont substance abuse treatment providers association;
(12) a mental health provider or a certified alcohol and drug counselor;
(13) a consumer in recovery from prescription abuse;
(14) a consumer receiving medical treatment for chronic pain; and
(15) any other member invited by the commissioner.

(c) The committee shall meet no less than quarterly in the first year, and no less than annually each following year, but may be convened at any time by the commissioner or the commissioner's designee.

(d) The committee shall issue a report to the senate and house committees on judiciary, the senate committee on health and welfare, and the house committee on human services no later than January 15th in 2008, 2010, and 2012.

NOTE: Exhibits E and G are the same due to a lettering error.

(e) This section shall sunset July 1, 2012 and thereafter the committee shall cease to exist. (Added 2005, No. 205 (Adj. Sess.), § 1.)

§ 4287. Rulemaking

The department shall adopt rules for the implementation of VPMS as defined in this chapter consistent with 45 C.F.R. Part 164, as amended and as may be amended, that limit the disclosure to the minimum information necessary for purposes of this act and shall keep the senate and house committees on judiciary, the senate committee on health and welfare, and the house committee on human services advised of the substance and progress of initial rulemaking pursuant to this section. (Added 2005, No. 205 (Adj. Sess.), § 1.)

NOTE: Exhibits E and G are the same due to a lettering error.

TITLE XVIII Public Health
CHAPTER 218A Controlled Substances
Kentucky

KRS § 218A.202 (2009)

218A.202. Electronic system for monitoring controlled substances -- Penalty for illegal use of system -- Pilot project -- Continuing education programs.

(1) The Cabinet for Health and Family Services shall establish an electronic system for monitoring Schedules II, III, IV, and V controlled substances that are dispensed within the Commonwealth by a practitioner or pharmacist or dispensed to an address within the Commonwealth by a pharmacy that has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy.

(2) A practitioner or a pharmacist shall not have to pay a fee or tax specifically dedicated to the operation of the system.

(3) Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the Cabinet for Health and Family Services the data required by this section in a timely manner as prescribed by the cabinet except that reporting shall not be required for:

(a) A drug administered directly to a patient; or

(b) A drug dispensed by a practitioner at a facility licensed by the cabinet provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.

(4) Data for each controlled substance that is dispensed shall include but not be limited to the following:

(a) Patient identifier;

(b) Drug dispensed;

(c) Date of dispensing;

(d) Quantity dispensed;

(e) Prescriber; and

(f) Dispenser.

(5) The data shall be provided in the electronic format specified by the Cabinet for Health and Family Services unless a waiver has been granted by the cabinet to an individual dispenser. The cabinet shall establish acceptable error tolerance rates for data. Dispensers shall ensure that reports fall within these tolerances. Incomplete or inaccurate data shall be corrected upon notification by the cabinet if the dispenser exceeds these error tolerance rates.

(6) The Cabinet for Health and Family Services shall only disclose data to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section. The Cabinet for Health and Family Services shall be authorized to provide data to:

(a) A designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

(b) A Kentucky peace officer certified pursuant to KRS 15.380 to 15.404, a certified or full-time peace officer of another state, or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person;

(c) A state-operated Medicaid program;

(d) A properly convened grand jury pursuant to a subpoena properly issued for the records;

(e) A practitioner or pharmacist who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide current patient;

NOTE: Exhibits E and G are the same due to a lettering error.

(f) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Medical Licensure, for any physician who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Board of Medical Licensure for improper prescribing practices;

2. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

3. In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area;

(g) In addition to the purposes authorized under paragraph (a) of this subsection, the Kentucky Board of Nursing, for any advanced registered nurse practitioner who is:

1. Associated in a partnership or other business entity with a physician who is already under investigation by the Kentucky Board of Medical Licensure for improper prescribing practices;

2. Associated in a partnership or other business entity with an advanced registered nurse practitioner who is already under investigation by the Board of Nursing for improper prescribing practices;

3. In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or

4. In a designated geographic area for which a report on a physician or another advanced registered nurse practitioner in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area; or

(h) A judge or a probation or parole officer administering a diversion or probation program of a criminal defendant arising out of a violation of this chapter or of a criminal defendant who is documented by the court as a substance abuser who is eligible to participate in a court-ordered drug diversion or probation program.

(7) The Department for Medicaid Services may use any data or reports from the system for the purpose of identifying Medicaid recipients whose usage of controlled substances may be appropriately managed by a single outpatient pharmacy or primary care physician.

(8) A person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except that:

(a) A peace officer specified in subsection (6)(b) of this section who is authorized to receive data or a report may share that information with other peace officers specified in subsection (6)(b) of this section authorized to receive data or a report if the peace officers specified in subsection (6)(b) of this section are working on a bona fide specific investigation involving a designated person. Both the person providing and the person receiving the data or report under this paragraph shall document in writing each person to whom the data or report has been given or received and the day, month, and year that the data or report has been given or received. This document shall be maintained in a file by each law enforcement agency engaged in the investigation; and

(b) A representative of the Department for Medicaid Services may share data or reports regarding overutilization by Medicaid recipients with a board designated in subsection (6)(a) of this section, or with a law enforcement officer designated in subsection (6)(b) of this section; and

(c) The Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

(9) The Cabinet for Health and Family Services, all peace officers specified in subsection (6)(b) of this section, all officers of the court, and all regulatory agencies and officers, in using the data for investigative or prosecution purposes, shall consider the nature of the prescriber's and dispenser's practice and the condition for which the patient is being treated.

(10) The data and any report obtained therefrom shall not be a public record, except that the Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B.

NOTE: Exhibits E and G are the same due to a lettering error.

(11) Intentional failure by a dispenser to transmit data to the cabinet as required by subsection (3), (4), or (5) of this section shall be a Class A misdemeanor for the first offense and a Class D felony for each subsequent offense.

(12) Intentional disclosure of transmitted data to a person not authorized by subsection (6) to subsection (8) of this section or authorized by KRS 315.121, or obtaining information under this section not relating to a bona fide specific investigation, shall be a Class D felony for the first offense and a Class C felony for each subsequent offense.

(13) The Commonwealth Office of Technology, in consultation with the Cabinet for Health and Family Services, shall submit an application to the United States Department of Justice for a drug diversion grant to fund a pilot project to study a real-time electronic monitoring system for Schedules II, III, IV, and V controlled substances. The pilot project shall:

(a) Be conducted in two (2) rural counties that have an interactive real-time electronic information system in place for monitoring patient utilization of health and social services through a federally funded community access program; and

(b) Study the use of an interactive system that includes a relational data base with query capability.

(14) Provisions in this section that relate to data collection, disclosure, access, and penalties shall apply to the pilot project authorized under subsection (13) of this section.

(15) The Cabinet for Health and Family Services may limit the length of time that data remain in the electronic system. Any data removed from the system shall be archived and subject to retrieval within a reasonable time after a request from a person authorized to review data under this section.

(16) (a) The Cabinet for Health and Family Services shall work with each board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances for the development of a continuing education program about the purposes and uses of the electronic system for monitoring established in this section.

(b) The cabinet shall work with the Kentucky Bar Association for the development of a continuing education program for attorneys about the purposes and uses of the electronic system for monitoring established in this section.

(c) The cabinet shall work with the Justice and Public Safety Cabinet for the development of a continuing education program for law enforcement officers about the purposes and users of the electronic system for monitoring established in this section.

218A.240. Controlled substances -- Duties and authority of state and local officers, Cabinet for Health and Family Services, and Kentucky Board of Pharmacy -- Civil proceedings -- Identification of trends.

(1) All police officers and deputy sheriffs directly employed full-time by state, county, city, urban-county, or consolidated local governments, the Department of Kentucky State Police, the Cabinet for Health and Family Services, their officers and agents, and of all city, county, and Commonwealth's attorneys, and the Attorney General, within their respective jurisdictions, shall enforce all provisions of this chapter and cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to controlled substances.

(2) For the purpose of enforcing the provisions of this chapter, the designated agents of the Cabinet for Health and Family Services shall have the full power and authority of peace officers in this state, including the power of arrest and the authority to bear arms, and shall have the power and authority to administer oaths; to enter upon premises at all times for the purpose of making inspections; to seize evidence; to interrogate all persons; to require the production of prescriptions, of books, papers, documents, or other evidence; to employ special investigators; and to expend funds for the purpose of obtaining evidence and to use data obtained under KRS 218A.202(7) in any administrative proceeding before the cabinet.

(3) The Kentucky Board of Pharmacy, its agents and inspectors, shall have the same powers of inspection and enforcement as the Cabinet for Health and Family Services.

NOTE: Exhibits E and G are the same due to a lettering error.

(4) Designated agents of the Cabinet for Health and Family Services and the Kentucky Board of Pharmacy are empowered to remove from the files of a pharmacy or the custodian of records for that pharmacy any controlled substance prescription or other controlled substance record upon tendering a receipt. The receipt shall be sufficiently detailed to accurately identify the record. A receipt for the record shall be a defense to a charge of failure to maintain the record.

(5) Notwithstanding the existence or pursuit of any other remedy, civil or criminal, any law enforcement authority may maintain, in its own name, an action to restrain or enjoin any violation of this chapter or to forfeit any property subject to forfeiture under KRS 218A.410, irrespective of whether the owner of the property has been charged with or convicted of any offense under this chapter.

(a) Any civil action against any person brought pursuant to this section may be instituted in the Circuit Court in any county in which the person resides, in which any property owned by the person and subject to forfeiture is found, or in which the person has violated any provision of this chapter.

(b) A final judgment rendered in favor of the Commonwealth in any criminal proceeding brought under this chapter shall estop the defendant from denying the essential allegations of the criminal offense in any subsequent civil proceeding brought pursuant to this section.

(c) The prevailing party in any civil proceeding brought pursuant to this section shall recover his or her costs, including a reasonable attorney's fee.

(d) Distribution of funds under this section shall be made in the same manner as in KRS 218A.420, except that if the Commonwealth's attorney has not initiated the forfeiture action under this section, his or her percentage of the funds shall go to the agency initiating the forfeiture action.

(6) The Cabinet for Health and Family Services shall make or cause to be made examinations of samples secured under the provisions of this chapter to determine whether any provision has been violated.

(7) (a) The Cabinet for Health and Family Services shall use the data compiled in the electronic system created in KRS 218A.202 for investigations, research, statistical analysis, and educational purposes and shall proactively identify trends in controlled substance usage and other potential problem areas. Only cabinet personnel who have undergone training for the electronic system and who have been approved to use the system shall be authorized access to the data and reports under this subsection. The cabinet shall notify a board responsible for the licensure, regulation, or discipline of each practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances, if a report or analysis conducted under this subsection indicates that further investigation about inappropriate or unlawful prescribing or dispensing may be necessary by the board.

(b) The cabinet shall develop criteria, in collaboration with the Board of Medical Licensure and the Board of Pharmacy, to be used to generate trend reports from the data obtained by the system. Meetings at which the criteria are developed shall be meetings, as defined in KRS 61.805, that comply with the open meetings laws, KRS 61.805 to 61.850.

(c) The cabinet shall, on a quarterly basis, publish trend reports from the data obtained by the system.

(d) Peace officers authorized to receive data under KRS 218A.202 may request trend reports not specifically published pursuant to paragraph (c) of this subsection. A report under this paragraph may be based upon the criteria developed under paragraph (b) of this subsection or upon any of the data collected pursuant to KRS 218A.202(4), except that the report shall not identify an individual prescriber, dispenser, or patient.

(e) No trend report generated under this subsection shall identify an individual prescriber, dispenser, or patient.

218A.245. Reciprocal agreements with other states to share prescription drug monitoring information.

(1) The secretary of the Cabinet for Health and Family Services may enter into reciprocal agreements with any other state or states of the United States to share prescription drug monitoring information if the other state's prescription drug monitoring program is compatible with the program in Kentucky. If the secretary

NOTE: Exhibits E and G are the same due to a lettering error.

elects to evaluate the prescription drug monitoring program of another state as authorized by this section, priority shall be given to a state that is contiguous with the borders of the Commonwealth.

(2) In determining compatibility, the secretary shall consider:

(a) The essential purposes of the program and the success of the program in fulfilling those purposes;

(b) The safeguards for privacy of patient records and its success in protecting patient privacy;

(c) The persons authorized to view the data collected by the program;

(d) The schedules of controlled substances monitored;

(e) The data required to be submitted on each prescription;

(f) Any implementation criteria deemed essential for a thorough comparison; and

(g) The costs and benefits to the Commonwealth in mutually sharing particular information available in the Commonwealth's database with the program under consideration.

(3) The secretary shall review any agreement on an annual basis to determine its continued compatibility with the Kentucky prescription drug monitoring program.

(4) The secretary shall prepare an annual report to the Governor and the Legislative Research Commission that summarizes any agreement under this section and that analyzes the effectiveness of that agreement in monitoring the dispensing of controlled substances in the Commonwealth.

(5) Any agreement between the cabinet and another state shall prohibit the sharing of information about a Kentucky resident, practitioner, pharmacist, or other prescriber for any purpose not otherwise authorized by this section or KRS 218A.202.